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Centre fast-tracks emergency approvals for foreign made COVID-19 vaccines

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The first 100 beneficiaries of such foreign vaccines shall be assessed for seven days for safety outcomes



The matter of augmenting the basket of vaccines available for fighting the pandemic as well as to accelerate the pace & coverage of domestic vaccination programme was discussed in the 23rd meeting of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) held on 11th April 2021, chaired by Dr. V K Paul, Member (Health), Niti Aayog.

The NEGVAC, after comprehensive deliberation, recommended that vaccines for COVID-19, which have been developed & are being manufactured in foreign countries and which have been granted emergency approval for restricted use by USFDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO(Emergency Use Listing) may be granted emergency use approval in India, mandating the requirement of post-approval parallel bridging clinical trial in place of conduct of local clinical trial as per the provisions prescribed under Second Schedule of the New Drugs & Clinical Trials Rules 2019.

Further, the first 100 beneficiaries of such foreign vaccines shall be assessed for seven days for safety outcomes before it is rolled out for further immunization programme within the country.

The Union Government, after due consideration, has accepted the recommendation of NEGVAC.

This decision will facilitate quicker access to such foreign vaccines by India & would encourage imports including import of bulk drug material, optimal utilization of domestic fill and finish capacity etc., which will in turn provide a fillip to vaccine manufacturing capacity and total vaccine availability for domestic.